

REMARKS

Applicants appreciate the cordial telephonic interviews accorded the undersigned attorney and Mr. Gordon R. Coons, Reg. No. 20,821, attorney for the licensee. Following the most recent interview on Thursday, October 2, 2003, an RCE has been filed. This preliminary amendment, filed contemporaneously with the RCE, addresses the June 3, 2003 final rejection issued in the parent reissue application, as well as the substantive points discussed during the telephonic interviews. Applicants are not aware of any substantive points discussed (e.g., outside of interview scheduling/availability/etc.) that are not contained in this amendment. Accordingly, this amendment constitutes a complete written statement of the reasons presented at the interview(s) as warranting favorable action, as required by 37 C.F.R. §1.133.

The Currently Pending Claims

Currently pending are claims 581-586, 588-596, 696 and 697, each directed to a composition comprising particulate apatite and claims 597-599, 601-612, 614-620, 623-639, and 674-695, each drawn to an article.

The Amendments to the Claims

Independent composition claim 581 has been amended to incorporate the subject matter of dependent claim 587, which dependent claim has now been canceled. Similarly, independent article claim 620 has been amended to incorporate the subject matter of dependent claim 621, which dependent claim 621 has now been canceled. Claim 624 has been amended so as to recite dependency upon claim 620. Lastly, new composition claims 696 and 697 have been added. Support for the new claims can be found in the subject specification at, for example, Example 6, as well as in the accompanying Declaration under 37 C.F.R. §1.132 of Edward S. Ahn.

The Rejections in the Prior Final Office Action

With respect to rejections based upon the prior art, claims 620, 622, 623 and 626-630 were indicated as rejected under 35 U.S.C. § 103(a) as being unpatentable over the Jarcho publication. Composition claims 581-586 were rejected under 35 U.S.C. 103(a) as being

unpatentable over the Nagai et al. patent. All of the pending claims were rejected under 35 U.S.C. § 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based.

Discussion of the Rejection of Claims 620, 622, 623 and 626-630

As claim 622 was not pending at the time of the final office action, it is believed that the apparent rejection of this claim is a typographical error, and will not be addressed.

As can be seen from the present amendments, claim 620 has been amended to incorporate the subject matter of dependent claim 621. Accordingly, inasmuch as dependent claim 621 was not rejected on the basis of prior art, it follows that presently amended claim 620 and the rejected claims dependent thereon, *i.e.* – 623 and 626-630, should also be allowable. The Examiner was advised in the initial telephonic interview that this amendment would be made, and it is understood that this amendment would obviate the rejection over the Jarcho publication.

Discussion of the Rejection of Claims 581-586 Under 35 U.S.C. § 103(a)

Independent claim 581 has been amended to incorporate the subject matter of dependent claim 587. Inasmuch as claim 587 was not rejected as being unpatentable over the Nagai et al. patent, it follows that composition claim 581 and the rejected claims dependent thereon (*viz.* – claims 582-586) should likewise be allowable. This amendment was discussed during the initial telephonic interview, and it is applicants' understanding that this will obviate the subject rejection.

Discussion of the Rejection of All Pending Claims Under 35 U.S.C. § 251

The analysis of this rejection follows the procedure set forth in the August 4, 2003 Memorandum to the Patent Examining Technology Center Directors and the Patent Examining Corps entitled "Updated Guidance as to Applying the Recapture Rule to Reissue Applications." This was provided to the undersigned attorney following a telephonic interview conducted with the Examiner discussing the June 3, 2003 final rejection in the parent reissue application.

Specifically, the analysis herein follows the second-numbered paragraph in I. Summary, specifically:

(1) the respective independent reissue claims are compared to the corresponding claims in the original application that were amended during prosecution.

(2) Then, the respective reissue claims are compared with the patent claims as regards whether the respective reissue claim omits any limitation that was added/argued during the original prosecution to overcome an art rejection.

(3) The reissue claims are then analyzed as to whether such claims recite a broader form of the key limitation added/argued during original prosecution to overcome an art rejection, therefore not entirely removing that key limitation.

Newly Added Composition Claims

As can be seen from a comparison of the only two independent compositions claims in the original application, claims 1 and 11, with the reissue claim 696 (Attachment A), reissue claim 696 is narrower than each of these two original independent claims (the additional limitations added in the reissue claim are set forth in boldface). Accordingly, reissue claim 696 does not include claim scope deemed to have been surrendered in the original prosecution, in this regard.

Secondly, as can be seen from the prosecution of the original application, the original independent composition claims were amended to recite that the crystal of the particulate apatite being claimed is “spherical.” Specifically, as to the rejection of independent claim 1 in the prosecution of the original application, applicants noted that the cited prior art neither anticipated nor made obvious claim 1 because of the terminology the composition comprising “particulate apatite having an average apatite crystal size of less than 100 nm, wherein the crystal is spherical.” For at least these reasons, it was noted that claim 1 as amended was not anticipated. (See Attachment B, the amendment in the original application.) Similarly, as regards the rejection of original independent claim 11, this was stated to be amended so as to be patentably distinguishable over the prior art, for at least the reasons set forth, *viz.* – a composition comprising particulate apatite having a “spherical crystal” (*see* attachment B – pages 9-11).

As can be seen from Attachment C (comparing newly added reissue claim 696 to original patent claims 1 and 9), newly added reissue claim 696 is narrower than the original patent claims 1 and 9 (patent claim 9 corresponding to application claim 11) in the limitations set forth in boldface in reissue claim 696.

Even further, as can be seen, newly added reissue claim 696 recites a broader form of the limitation argued during the original prosecution, fully consistent with *Ex parte Eggert*, Appeal No. 2001-0790 (Bd. Pat. App. & Inter. May 29, 2003) and as set forth in the Federal Circuit's decision in *Pannu v. Storz Instruments Inc.*, 258 Fed. 3rd 1366 (Fed. Cir. 2001). Indeed, newly added claim 696 presents the same factual situation as is set forth in the August 4, 2003 Memorandum in Paragraph 2 of the Summary. In the example set forth in that Summary, the key limitation added was "an orange peel" and the reissue claim recited a "citrus fruit peel." That reissue claim could not be rejected on recapture grounds as the Memorandum states.

Similarly, during original prosecution, a recitation that the apatite crystal is "spherical" was added (see patent claims 1 and 9), while newly added composition claim 696 broadens the claim to recite that the structure is from "needle-like to spherical", consistent with the patent specification, specifically Example 6, as mentioned above. The recitation in dependent claim 697 that the structure has a length:width aspect ratio in the range of from 2.3 to 5.9 is inherent in the working Examples. Specifically, the accompanying Declaration of Dr. Edward Ahn, one of the inventors, establishes the support for the inherency.

The Article Claims

There were no independent article claims presented in the original prosecution. Accordingly, it is not seen how re-issue independent article claims, *i.e.*, 597, 620 and 674 represent any recapture of subject matter surrendered in original prosecution.

Moreover, the prosecution in the original application makes it clear that the inclusion of the limitation that the apatite crystal is "spherical" in independent application composition claims 1 and 11 was not introduced to overcome any art rejection concerning the article claims depending from such independent composition claims. Specifically, as can be seen in the amendment (Attachment B), only dependent article claims 26-32 were rejected over prior art,

i.e., claims 26 and 28-32 being rejected as anticipated under 35 U.S.C. § 102(b) by the Saita et al. reference and claim 27 being rejected as being unpatentable under 35 U.S.C. § 103(a) over Saita et al. As regards the latter rejection (see Amendment, page 12 – Attachment B), applicants did not argue the patentability of article claim 27 (which was dependent upon composition claim 11) on the basis of prior art applicable to claim 27. Rather, as can be seen, applicants' attorney merely stated that claims 1 and 11 were not rejected on this ground so that "it is believed that the rejection of these claims on this ground is improper." (Amendment, page 12). There is no reference whatsoever to the claim amendments made to either application claim 1 or 11. Rather, the argument was based upon the inappropriateness of the rejection itself.

Regarding the rejection under Section 102, involving article claim 26 (dependent on claim 1) and 28-32 (dependent, directly or indirectly on claim 26), no reference whatever was made to the shape of the crystal in amended claim 1. What was stated is that claim 1 was amended to recite that "as precipitated, comprising particulate apatite having an average apatite crystal size of less than 100 nm." The average crystal size limitation has been retained, except that, as can be seen, each independent article claim has been broadened by reciting that the average crystal size is less than 250 nm, such broadening being contemplated and sanctioned by the precedent discussed herein.

Reissue Composition Claim 581 and the Claims Dependent Thereon

First of all, as can be seen from Attachment D, pending reissue composition claim 581 is narrower than the original application claims 1 and 11. Accordingly, reissue composition claim 581 is not subject to improper recapture in this regard.

Secondly, as can be seen by Attachment E, reissue composition claim 581 is narrower than both patent claims 1 and 9, whether such patent claims are compared singly or collectively, in the limitations set forth in boldface in re-issue claim 581. Reissue composition claim 581 does not include the limitation that the crystal is "spherical." And, as previously noted, applicants do not contest the fact that this limitation was added to overcome the cited prior art.

However, it is submitted that the subject reissue composition claim 581 is nevertheless not properly subject to recapture. Reissue composition claim 581 includes a limitation as to the

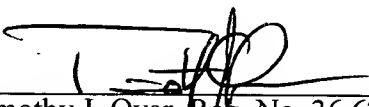
surface area of the hydroxyapatite particles and thereby implicitly retains the limitation as to the structure of the crystal. There is a relationship between surface area and morphology (shape), therefore there was no surrender during original prosecution of subject matter which is now attempting to be recaptured. Indeed, as is set forth in the accompanying Declaration of Dr. Ahn, the surface area of the hydroxyapatite particles decreases as the aspect ratio of the needle-like structure increases. Thus, the surface area of the particles is related to the surrender (See the Recapture Memorandum, Page 6-Section III).

Even further, it is submitted that any limitation of the particulate apatite in composition claim 581 relates to the surrender. This is not a situation like the one illustrated in Section IV of the new Reissue Recapture Guidelines where one element, C, in a multi-element claim, i.e., ABC is replaced by element X. There is only one "element", i.e., the particulate apatite.

Conclusion

It is respectfully submitted that the present amendment obviates the two rejections based on prior art due to the amendment of the claims to incorporate the subject matter in the dependent claims found allowable. As to the recapture issue, applicants believe that none of the presently pending composition or article claims are properly subject to recapture. However, the Examiner is invited to telephone the undersigned attorney should any issues remain. Indeed, to expedite prosecution in this application, applicants stand ready to cancel any claims where issues may remain, reserving the right to file a further continuing application to address the patentability of such claims.

Respectfully submitted,



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Date: October 30, 2003



ATTACHMENT A

COMPOSITION
CLAIM COMPARISON
ORIGINAL APPLICATION-REISSUE

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ORIGINAL APPLICATION CLAIMS (rearranged to facilitate a side-by-side comparison)	REISSUE CLAIM (rearranged to facilitate a side-by-side comparison)
<p>1. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystal size of less than 250 nm 	<p>696. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystallite size of less than 150 nm • an average apatite particle size of less than 1 μm • a surface area of at least 40 m²/g • wherein the particulate apatite undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours • the crystal apatite having a structure from needle-like to spherical
<p>11. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40 m²/g 	<p>696. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40 m²/g • an average crystallite size of less than 150 nm • an average apatite particle size of less than 1 μm • wherein the particulate apatite undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours • the crystal apatite having a structure from needle-like to spherical



ATTACHMENT B

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NOV 07 2003
TC 1700

ATTORNEY'S DOCKET NO: M0925/7041 TJO
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jackie Y. Ying et al.
Serial No: 09/007,930
Filed: January 16, 1998
For: NANOCRYSTALLINE APATITES AND COMPOSITES, PROSTHESES
INCORPORATING THEM, AND METHOD FOR THEIR PRODUCTION
Examiner: C. Koslow
Art Unit: 1755

COPY

AS FILED

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on the 21st day of June 1999.

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT

COPY

Sir:

In response to the Office Action dated January 19, 1999, please amend the above-identified application as follows. Reconsideration is respectfully requested.

In the Specification

Please amend the specification as follows.

On page 8, line 3, please delete "carbonates" and insert therefor -- carbonate --.

On page 8, line 4, please delete "apatite can" and insert therefor -- ions --.

On page 12, line 4, please delete " $M_{10}^{2+}(ZO_y)_6^{3-}X^{2-}$ " and insert therefor -- $M_{10}^{2+}(ZO_y)_6^{3-}X^{2-}$ --.

On page 12, line 5, please delete "Na, K,".

On page 12, line 5, please insert after "Cd, etc." -- where M can be substituted with Na and/or K and consequently the formula can be substituted with an appropriate number of vacancies and/or anions, as known by one of ordinary skill in the art --.

On page 12, line 5, please delete "SiO₄, SO₄, CO₃, BO₃, etc.;" and insert therefor -- etc.
where ZO_y can be substituted with SiO₄, SO₄, CO₃, BO₃, etc. to balance a total charge of cations, as known by one of ordinary skill in the art; --

- On page 12, line 9, please delete " C_{10} " and insert therefor -- Ca_{10} --.
- On page 12, line 10, please delete " $(Sr,Ce)_5$ " and insert therefor -- $(Sr,Ce)_5$ --.
- On page 12, line 11, please delete " $(Ce,Ca)_5$ " and insert therefor -- $(Ce,Ca)_5$ --.
- On page 12, line 11, please delete " $(Y,Ca)_5$ " and insert therefor -- $(Y,Ca)_5$ --.
- On page 12, line 12, please insert after " $[AsO_4,PO_4]$ " -- $_3$ --.
- On page 12, line 13, please insert after " (AsO_4) " -- $_3$ --.
- On page 12, line 14, please insert after " $Ca_5(AsO_4)_3$ " -- $_3$ --.
- On page 12, line 15, please insert after " $(AsO_4)_3$ " -- $_3$ --.
- On page 21, line 3, please delete "0.100 M" and insert therefor -- 0.167 M --.
- On page 21, line 4, please delete "0.167 M" and insert therefor -- 0.100 M --.
- On page 30, line 5, please delete "brushite ($CaPO_3OH$)" and insert therefore -- $(CaHPO_4 \cdot 2H_2O)$ --.

In the Claims

Please cancel claims 2 and 3.

Please amend the following claims.

1. (Amended) A composition, as precipitated comprising particulate apatite having an average apatite crystal size of less than [250] 100 nm, wherein the crystal is spherical.
4. (Amended) [A] The composition [as in] of claim 1 comprising particulate apatite having an average apatite crystal size of less than 50 nm.
5. (Amended) [A] The composition [as in] of claim 1 comprising particulate apatite having an average apatite crystal size of less than 30 nm.
6. (Amended) [A] The composition [as in] of claim 1 comprising particulate apatite having an average apatite crystal size of less than 20 nm.

7. (Amended) A composition as in claim 1 [comprising densified crystalline apatite] wherein the particulate apatite is densified.
8. (Amended) [A] The composition [as in] of claim 1 comprising apatite having an average particle size of less than 1 μm .
9. (Amended) [A] The composition [as in] of claim 1 comprising apatite having an average particle size of less than 0.5 μm .
10. (Amended) [A] The composition [as in] of claim 1 comprising apatite having an average particle size of less than 0.25 μm .
11. (Amended) A composition comprising particulate apatite having a surface area of at least 40 m^2/g and a spherical crystal.
12. (Amended) [A] The composition [as in] of claim 11 comprising particulate apatite having a surface area of at least 100 m^2/g .
13. (Amended) [A] The composition [as in] of claim 11 comprising particulate apatite having a surface area of at least 150 m^2/g .
14. (Amended) [A] The composition [as in] of claim 11 that undergoes apatite phase decomposition of less than 10 % when exposed to conditions of at least 1000°C for at least 2 hours.
15. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 5 % when exposed to conditions of at least 1000°C for at least 2 hours.
16. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase

decomposition of less than 3 % when exposed to conditions of at least 1000°C for at least 2 hours.

17. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 10 % when exposed to conditions of at least 1100°C for at least 2 hours.

18. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 5 % when exposed to conditions of at least 1100°C for at least 2 hours.

19. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 3 % when exposed to conditions of at least 1100°C for at least 2 hours.

20. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 10 % when exposed to conditions of at least 1200°C for at least 2 hours.

21. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 5 % when exposed to conditions of at least 1200°C for at least 2 hours.

22. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 3 % when exposed to conditions of at least 1200°C for at least 2 hours.

23. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 10 % when exposed to conditions of at least 1300°C for at least 2 hours.

24. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 5 % when exposed to conditions of at least 1300°C for at least 2 hours.

25. (Amended) [A] The composition [as in] of claim 14 that undergoes apatite phase decomposition of less than 3 % when exposed to conditions of at least 1300°C for at least 2 hours.

26. (Amended) An article having a dimension of at least 0.5 cm made up of [a] the composition [as in] of claim 1.
27. (Amended) An article having a dimension of at least 0.5 cm made up of [a] the composition [as in] of claim 11.
28. (Amended) [An] The article [as in] of claim 26 [comprising consolidated] wherein the particulate apatite is consolidated.
29. (Amended) [An] The article [as in] of claim 26, formed into the shape of a prosthesis.
30. (Amended) [An] The article [as in] of claim 26 that is [at least a part of] a prosthesis.
31. (Amended) [An] The article [as in] of claim 26 comprising an exterior coating on a prosthesis.
32. (Amended) [An] The article [as in] of claim 31 comprising an exterior coating, on a prosthesis, of at least 0.5 micron in thickness.
33. (Amended) [An] The article [as in] of claim 26 having a theoretical density of at least 90%.
34. (Amended) [An] The article [as in] of claim 26 having a theoretical density of at least 95%.
35. (Amended) [An] The article [as in] of claim 26 having a theoretical density of at least 98%.
36. (Amended) [An] The article [as in] of claim 27 having a porosity of at least 20%.
37. (Amended) [An] The article [as in] of claim 27 having a porosity of at least 30%.

38. (Amended) [An] The article [as in] of claim 27 having a porosity of at least 50%.
39. (Amended) [An] The article [as in] of claim 27 having a porosity of at least 75%.
40. (Amended) [A] The densified article [as in] of claim 27 having compressive strength of at least about 150 MPa.
41. (Amended) [A] The densified article [as in] of claim 27 having compressive strength of at least about 500 MPa.
42. (Amended) [A] The densified article [as in] of claim 27 having compressive strength of at least about 700 MPa.
43. (Amended) [A] The densified article [as in] of claim 40, having a density of at least about 90 %.
44. (Amended) [A] The densified article [as in] of claim 40, having a density of at least about 95% [or 98%].

Please add the following claims

45. The densified article of claim 40, having a density of at least about 98%.
46. The article of claim 26 that is a part of a prosthesis.

REMARKS

Claims 1-44 stand pending in this application. Claims 2 and 3 have been canceled. Claims 1 and 4-44 have been amended. Claims 45 and 46 have been added.

Objection to the Specification

An information disclosure statement is attached to this response.

The proposed amendments to lines 3 and 4 of page 21 of December 11, 1998 were not entered by the Patent Office. Lines 2-4 of page 21 were intended to describe the preparation of nanocrystalline hydroxyapatite at two different concentrations. The specification teaches that in one embodiment it is important to maintain the ratio of Ca:P at 10:6 (page 20, line 30). The line "900 ml of a 0.100 M solution of $\text{Ca}(\text{NO}_3)_2$ was added to 900 ml of 0.167 M aqueous $(\text{NH}_4)_2\text{HPO}_4$ solution..." represents a typographical error because this provides a Ca:P ratio of 6:10 whereas the addition of 900 ml of a 0.167 M solution of $\text{Ca}(\text{NO}_3)_2$ to 0.100 M of $(\text{NH}_4)_2\text{HPO}_4$ would achieve the proper Ca:P ratio of 10:6.

The proposed amendment to replace the second occurrence of " (CaPO_3OH) " on page 30, line 5 with " CaHPO_4 " was not entered by the Patent Office. This substitution has been amended to replace the second occurrence of " (CaPO_3OH) " with " $\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$ " as suggested by the Patent Office.

As suggested by the Patent Office, the first occurrence of "apatite" on page 8, line 4, has been replaced with "ions" and "carbonates" on page 8, line 3 has been replaced with "carbonate."

The formula $\text{M}_{10}^{2+}(\text{ZO}_y)_6^{3-} \text{X}^{2-}$ on page 12, line 4 has been replaced with $\text{M}_{10}^{2+}(\text{ZO}_y^{3-})_6 \text{X}^{2-}$. This new formula clarifies that ZO_y has a charge of 3- and not $(\text{ZO}_y)_6$, as is understood by one of ordinary skill in the art.

The Patent Office has objected to certain informalities on page 12, lines 4-15. "M = Ca, Ba, Sr, Mg, Na, K, Pb, Cd, etc.;" has been replaced with "M = Ca, Ba, Sr, Mg, Pb, Cd, etc. where M can be substituted with Na and/or K and consequently the formula can be substituted with an appropriate number of vacancies and/or anions, as known by one of ordinary skill in the art." " $\text{ZO}_y = \text{PO}_4, \text{AsO}_4, \text{VO}_4, \text{SiO}_4, \text{SO}_4, \text{CO}_3, \text{BO}_3, \text{etc.};$ " has been replaced with " $\text{ZO}_y = \text{PO}_4, \text{AsO}_4, \text{VO}_4 \text{ etc.}$ where ZO_y can be replaced with any one of $\text{SiO}_4, \text{SO}_4, \text{CO}_3, \text{BO}_3, \text{etc.}$ to balance a total charge of cations, as known by one of ordinary skill in the art;". As suggested by the Patent Office, "C10" on line 9 has been replaced with "Ca10." "Ce.." has been replaced with "Ce" and "Ca.." has been replaced with "Ca". In the first compounds of lines 14 and 15, the subscript 5 has been inserted for

(AsO₄).

Rejection of Claims 1-44 under 35 U.S.C. §112, second paragraph

As suggested by the Patent Office, all claims reciting "A _____ as in claim..." have been replaced with "The _____ of claim..."

Claim 44 has been amended to delete "or 98%." New claim 45 recites a "density of at least 98%."

The Patent Office states that claims 8-10 are indefinite, stating that the meaning of "particle" is unclear. It is believed that one of ordinary skill in the art would understand "particle" to be a discrete entity. Indeed, the specification teaches that particles can be larger than crystals, i.e. an agglomerate of crystals. In another embodiment, the particle can also be a crystal. Particle size can be minimized such that the nanocrystalline apatites have "an average particle size that approaches the average crystal size of the material" (page 11, lines 26-27) and where "individual crystals define individual particles" (page 11, line 29). Thus, it is believed that one of ordinary skill in the art will understand the meaning of claims 8-10 and 1-6.

The Patent Office objects to the relationship of claim 7, which recites crystalline apatite, to claim 1, which recites particulate apatite. Claim 7 has been amended to recite "wherein the particulate apatite is densified."

Claims 26 and 27 have been amended to recite "An article... made up of the composition of claim ____."

As suggested by the Patent Office, Claim 28 has been rewritten to recite, "The article of claim 26 wherein the particulate apatite is consolidated."

The Patent Office objects to claim 29, stating that it is unclear how the article of claim 26 is formed into the shape of a prosthesis. It is believed that in reading the specification that one of ordinary skill in the art would note many ways to form articles, e.g. densification (pages 15-16), consolidation (page 16), and would know how to form articles of any shape.

The Patent Office objects to claim 30 because an article cannot be both a prosthesis or part of a prosthesis. Claim 30 has been amended to recite the article "that is a prosthesis." New claim 46

recites an article "that is a part of a prosthesis."

The Patent Office objects to claims 31 and 32 because "a coating is not an article." The specification clearly states, however, that the article can be "an exterior coating on a prosthesis" (page 15, line 30). It is believed that it would be understood by one of ordinary skill in the art that an article can define a large variety of tangible objects, including a coating.

Rejection of Claims 1-3 under 35 U.S.C. §102(b) over Applicant's specification

Claims 1-3 stand rejected under 35 U.S.C. §102(b) as being anticipated by the specification on page 23. The Applicants respectfully traverse this rejection as follows.

Claim 1 has been amended to recite a composition comprising "particulate apatite having an average apatite crystal size of less than 100 nm, wherein the crystal is spherical." Support for "spherical" can be found in the specification on page 26, lines 30-32 ("Needle-like and rod-like structures redissolve and are recrystallized in more orderly morphologies such as spheres...").

It is not observed where the specification discloses that the Aldrich product comprises a crystal that is spherical, and it is believed that this commercially available product is elongated in the form of "whiskers."

For at least these reasons, claim 1, as amended, is not anticipated by the specification on page 23. Claims 2 and 3 have been canceled. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claim 11 under 35 U.S.C. §103(a) over Applicant's specification

Claim 11 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Applicant's specification on page 23. The Applicants respectfully traverse this rejection as follows.

Claim 11 has been amended to recite a composition comprising particulate apatite having a "spherical crystal." It is believed that the commercially available product listed on page 23 are not spherical but have an elongated shape. This specification cites no suggestion or motivation on the part of the manufacturer of the commercially available product to provide spherical crystals.

For at least these reasons, claim 11, as amended, is patentably distinguishes over the

Applicant's specification on page 23. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 1, 2 and 8-10 under 35 U.S.C. §102(b) as being anticipated by Ichitsuka et al.

Claims 1, 2 and 8-10 stand rejected under 35 U.S.C. §102(b) as being anticipated by Ichitsuka et al. The Applicants respectfully traverse this rejection as follows.

As discussed previously, claim 1 has been amended to recite a composition comprising "particulate apatite having an average apatite crystal size of less than 100 nm..." Due to this amendment, claim 2 has been canceled.

For at least these reasons, claim 1, as amended, is not anticipated by Ichitsuka et al. Claims 8-10 depend from claim 1, and for at least these same reasons, it is believed that claims 8-10 are not anticipated by Ichitsuka et al. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 1-5 and 8-10 under 35 U.S.C. §102(b) as being anticipated by Nagai et al.

Claims 1-5 and 8-10 stand rejected under 35 U.S.C. §102(b) as being anticipated by Nagai et al. The Applicants respectfully traverse this rejection as follows.

Claim 1 has been amended to recite a composition comprising "particulate apatite having an average apatite crystal size of less than 100 nm, wherein the crystal is spherical" as discussed previously. In contrast, Nagai teaches forming elongated crystals having a "ratio of length to width of 3 to 10" (e.g. column 6, line 64; column 7, lines 18-19). By this large ratio of length to width, it is not observed where Nagai discloses forming spheres.

For at least these reasons, claim 1, as amended, is not anticipated by Nagai et al. Claims 2 and 3 have been canceled. Claims 4, 5 and 8-10 depend from claim 1, and for at least these same reasons, it is believed that claims 4, 5 and 8-10 are not anticipated by Nagai et al. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 6 and 11-13 under 35 U.S.C. §103(a) as being unpatentable over Nagai

Claims 6 and 11-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Nagai et al. The Applicants respectfully traverse this rejection as follows.

Claim 11 has been amended to recite particulate apatite having a spherical crystal. In contrast, Nagai teaches forming elongated crystals having a “ratio of length to width of 3 to 10” (e.g. column 6, line 64; column 7, lines 18-19). Forming elongated crystals having such a large ratio of length to width is a clear teaching away from claim 11, as amended.

For at least these reasons, claim 1 claim 11, as amended patentably distinguish over Nagai et al. Claim 6 depends from claim 1, which does not stand rejected on this ground thus the rejection of claim 6 on this ground is believed to be improper. Claims 12 and 13 depend from claim 11, and for at least these same reasons, it is believed that claims 6, 12 and 13 patentably distinguish over Nagai et al. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 1-3 and 7-10 under 35 U.S.C. §102(b) as being anticipated by Niwa et al.

Claims 1-3 and 7-10 stand rejected under 35 U.S.C. §102(b) as being anticipated by Niwa et al. The Applicants respectfully traverse this rejection as follows.

Claim 1 has been amended to recite a composition “as precipitated, comprising particulate apatite having an average apatite crystal size of less than 100 nm...” The present invention discloses formation of small, apatite crystals free from any step of removing or excluding larger, undesired particles. In contrast, Niwa discloses removing coarser particles by passing all particles through a mesh (e.g. column 9, lines 52-53; column 10, lines 22-23; column 10, lines 55-56, etc.). It is not observed where Niwa prepares particulate apatite having an average apatite crystal size of less than 100 nm, as precipitated.

For at least these reasons, it is believed that claim 1, as amended, is not anticipated by Niwa. Claims 2 and 3 have been canceled. Claims 7-10 depend from claim 1 and for at least these same reasons, claims 7-10 are not anticipated by Niwa. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 1, 7-10, 26 and 28-32 under 35 U.S.C. §102(b) as being anticipated by Saita et al.

Claims 1, 7-10, 26 and 28-32 stand rejected under 35 U.S.C. §102(b) as being anticipated by Saita et al. The Applicants respectfully traverse this rejection as follows.

As discussed above, claim 1 has been amended to recite a composition "as precipitated, comprising particulate apatite having an average apatite crystal size of less than 100 nm..." In contrast, Saita states "...particles having a large particle size are removed off. By this method, any contamination of particles having unexpectedly large particle size can effectively be removed." (column 3, lines 19-20). It is not observed where the apatites of Saita are formed without this removal step, as recited in claim 1, as amended.

For at least these reasons, claim 1 is not anticipated by Saita et al. Claims 7-10, 26 and 28-32 depend from claim 1 and for at least these same reasons, claims 7-10, 26 and 28-32 are not anticipated by Saita et al. It is believed that the rejection has been overcome and it is respectfully requested that the rejection be withdrawn.

Rejection of Claims 2-6, 13-22 and 27 under 35 U.S.C. §103(a) as being unpatentable over Saita et al.

Claims 2-6, 13-22 and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by Saita et al. Claims 2-6 depend from and contain the limitations of independent claim 1, and claims 13-22 and 27 depend from and contain the limitations of independent claim 11. Claims 1 and 11 do not stand rejected on this ground, thus it is believed that the rejection of these claims on this ground is improper, and it is respectfully requested that the rejection be withdrawn.

A favorable office action is hereby respectfully requested.

If, for any reason, the Examiner is of the opinion that a telephone conversation with Applicants' representative would expedite prosecution, the Examiner is kindly invited to contact the undersigned at (617) 720-3500.

Please charge any fee or fee deficiency occasioned by this amendment to Deposit Account No. 23/2825.

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Art Unit 1755

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Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Timothy J. Oyer", is written over a horizontal line.

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X06/19/99



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ATTACHMENT C

COMPOSITION
CLAIM COMPARISON
PATENT-REISSUE

PATENT CLAIM (rearranged to facilitate a side-by-side comparison)	REISSUE CLAIM (rearranged to facilitate a side-by-side comparison)
<p>1. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystal size of less than 100 nm, • wherein the crystal is spherical 	<p>696. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystallite size of less than 150 nm • the crystal apatite having a structure from needle-like to spherical • a surface area of at least 40m²/g • an average apatite particle size of less than 1 μm • wherein the particulate apatite undergoes phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours
<p>9. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40 m²/g • spherical crystal 	<p>696. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40m²/g • the crystal apatite having a structure from needle-like to spherical • an average apatite crystallite size of less than 150 nm • an average apatite particle size of less than 1 μm • wherein the particulate apatite undergoes apatite phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours



ATTACHMENT D

COMPOSITION
CLAIM COMPARISON
ORIGINAL APPLICATION-REISSUE

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ORIGINAL APPLICATION CLAIMS (rearranged to facilitate a side-by-side comparison)	REISSUE CLAIM (rearranged to facilitate a side-by-side comparison)
1. A composition comprising particulate apatite having <ul style="list-style-type: none">an average apatite crystal size of less than 250 nm	581. A composition comprising particulate apatite having <ul style="list-style-type: none">an average crystal size of less than 150 nman average apatite particle size of less than 1 μma surface area of at least 40 m²/gwherein the particulate apatite undergoes apatite phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours
11. A composition comprising particulate apatite having <ul style="list-style-type: none">a surface area of at least 40 m²/g	581. A composition comprising particulate apatite having <ul style="list-style-type: none">a surface area of at least 40 m²/gan average crystal size of less than 150 nman average apatite particle size of less than 1 μmwherein the particulate apatite undergoes apatite phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours

ATTACHMENT E

COMPOSITION CLAIM COMPARISON PATENT-REISSUE

PATENT CLAIM (rearranged to facilitate a side-by-side comparison)	REISSUE CLAIM (rearranged to facilitate a side-by-side comparison)
<p>1. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystal size of less than 100 nm, wherein the crystal is spherical 	<p>581. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • an average apatite crystal size of less than 150 nm • a surface area of at least 40m²/g • an average apatite particle size of less than 1 μm • wherein the particulate apatite undergoes apatite phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours
<p>9. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40 m²/g and a spherical crystal 	<p>581. A composition comprising particulate apatite having</p> <ul style="list-style-type: none"> • a surface area of at least 40m²/g • an average apatite crystal size of less than 150 nm • an average apatite particle size of less than 1 μm • wherein the particulate apatite undergoes apatite phase decomposition of less than 10% when exposed to conditions of at least 1300°C for at least 2 hours